REMARKS

Claims 1-17 are pending in the instant application. Claims 6, 10-14, 16 and 17 have been withdrawn from consideration and subsequently canceled without prejudice by Applicants in this amendment. Claims 1-5, 7 and 9 have been rejected. Claims 1 and 15 have been amended. Claim 3 has been canceled. New claims 18, 19 and 20 have been added. Support for these amendments is provided in the specification at page 14, lines 9-16, page 14, line 17 through page 16, line 30, page 62, line 6 through page 63, line 16, page 65, lines 7-26, Examples 1 and 2 and the Sequence Listing. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The restriction requirement mailed September 22, 2003 has been made final. Thus, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 6, 10-14, 16 and 17. Applicants have also amended the claims to be drawn to the elected sequence. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Disclosure

The disclosure has been objected to for inclusion of embedded hyperlinks. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the specification to inactivate any hyperlinks or other forms of browser executable code. No new matter has been added by this amendment. Withdrawal of this objection is respectfully requested in light of these amendments.

III. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. 112, second paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner suggests that the claims are vague and indefinite because they claim more than was elected. Thus, Applicants have amended the claims to be drawn to the elected subject matter.

Further, the Examiner suggests that the recitation of "selectively hybridizes" is vague, indefinite and incomplete because the term is a relative one and no frame of reference is

given.

Applicants respectfully disagree since what is meant by "selectively hybridizes" is described in detail in the specification at page 14, lines 9-16. However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to delete this phrase and to clarify that the nucleic acid molecule shares 90% identity and hybridizes under stringent conditions. Detailed teachings of what is meant by stringent hybridization conditions is provided in the specification at page 14, line 17 through page 16, line 30.

In addition, the Examiner suggests that the recitation in claim 15 of "means for determining the presence of the nucleic acid molecule of claim 1" is vague and indefinite because such means are not clearly defined. The Examiner suggests that it cannot be determined from the specification what means are contemplated.

Applicants respectfully disagree.

Exemplary means contemplated for determining the presence of a nucleic acid sequence are described in the patent application at page 95, line 10, through page 96, line 9.

MPEP § 2173 is quite clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. The content of the application in this case makes clear what is meant by stringent hybridization conditions and sets forth various means for detecting a nucleic acid in accordance with the claimed kits, thus meeting the requirements of 35 U.S.C. § 112, second paragraph. Further clarification in the claims is not required.

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph is respectfully requested in light of the above remarks and the amendments to the claims.

IV. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that parts (c) and (d) of claim 1, drawn to nucleic acids which selectively hybridize to SEQ ID NO:64 or those having 60% identity to SEQ ID NO:64 cover a large genus of related nucleic acids which are not described and were not in applicants

possession. In addition, with respect to claim 3, the Examiner suggests that the specification fails to describe the complete genomic DNA corresponding to the cDNA of SEQ ID NO:64.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled claim 3.

Further, Applicants have amended claim 1, part (c), to state that the nucleic acid sequence has 90% identity and hybridizes under stringent conditions. Applicants have amended part (d) of claim 1 to state that the nucleic acid sequence has 60% identity over its entire length. Applicants have also amended claim 1 to include part (e) drawn to a nucleic acid molecule which is an allelic variant of a nucleic acid of SEQ ID NO: 63 or 64 encoding an amino acid sequence of SEQ ID NO:127 in accordance with teachings at page 34, lines 3-22 of the specification and the sequence listing showing SEQ ID NO:63 to be a subsequence of SEQ ID NO:64, part (f) drawn to a nucleic acid molecule that encodes an amino acid sequence having at least 90% sequence identity to SEQ ID NO:127 in accordance with teachings at page 65, lines 6-26 and to state that the nucleic acid molecule is detectably expressed in breast tumor tissues in accordance with teachings at page 116-121 of the instant specification.

Detailed methodologies for ascertaining sequences which meet

the structural and functional limitations of the instant amended claims are set forth in the specification at page 13, lines 5-29, and page 14, line 11 through page 16, line 32 and Example 1. Further methods for assessing percent sequence identity and/or the ability of a nucleic acid sequence to hybridize under stringent conditions to a disclosed reference sequence are performed routinely by those skilled in the art. Thus, upon discovery of the instant claimed nucleic acid sequence of SEQ ID NO:81 and its expression in lung tumor tissues, applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well.

Thus, the instant specification and the claims as amended meet the "essential goal" of the written description requirements of 35 U.S.C. § 112, first paragraph as set forth in MPEP § 2163.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1-5, 7-9 and 15 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-9 and 15 have been rejected under 35 U.S.C. §

101 and 35 U.S.C. § 112, first paragraph, as the Examiner suggests that the instant specification does not disclose a specific, substantial and credible utility for the nucleic acid sequence of SEQ ID NO:64.

It is respectfully pointed out, however, that SEQ ID NO:63 is a subsequence of SEQ ID NO:64. Thus, data presented is Example 1 for SEQ ID NO:63 is also relevant with respect to utility of SEQ ID NO:64.

Further, the instant application claims priority to provisional U.S. Application Serial No. 60/249,998, which as stated at page 1 of the instant application is incorporated by reference in its entirety into the instant application. This provisional application sets forth mRNA subtraction experiments in breast tissue demonstrating differential expression of these markers in breast cancer as compared to normal tissue. Figure 20 (SEQ ID NO:2) of this provisional application is identical to SEQ ID NO:63 of the instant application.

The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980).

Clearly identification of SEQ ID NO:63 and 64 as differentially expressed in cancer tissue constitutes a pharmacological activity relevant to the asserted use as a diagnostic for cancer, thus satisfying the utility requirement.

Withdrawal of these rejections under 35 U.S.C. § 101 and 112, first paragraph, is therefore respectfully requested.

V. Rejection of Claims 1, 2, 4, 5 and 7-9 under 35 U.S.C. 102(b)

Claims 1, 2, 4, 5 and 7-9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/58675. The Examiner suggests that WO 99/58675 discloses the cloning of a human cDNA (SEQ ID NO:1802) which has a region of about 88% identity with instant SEQ ID NO:64 across a portion of about 5% of SEQ ID NO:64. Thus, the Examiner suggests that the nucleic acid taught by WO 99/58675 cannot be distinguished from that being claimed in claim 1 since SEQ ID NO:1802 would be expected to selectively hybridize to SEQ ID NO:64 and has at least 60% sequence identity to SEQ ID NO:64. The Examiner also suggests that this sequence is a cDNA, is human and that the reference further teaches vectors comprising the cDNA, a host cell comprising the vector and expression of the encoded protein.

Accordingly, in an earnest effort to advance the prosecution

and to clarify distinctions between the instant invention and the teachings of WO 99/58675, Applicants have amended claim 1 to clarify that nucleic acid molecules of the present invention must exhibit 60% percent identity over their entire length to a nucleic acid of (a) or (b), not merely 5%, or exhibit 90% identity and hybridize under stringent conditions to a nucleic acid of (a) or (b). Further, the claim as amended requires that the nucleic acid molecule be detectably expressed in breast tumor tissue. Support for these amendments is provided in the specification at page 14-16, page 34 and Example 1.

Since WO 99/58675 does not teach a nucleic acid molecule with these characteristics, it cannot anticipate the claims as amended.

Withdrawal of this rejection under 35 U.S.C. § 102(b) is therefore respectfully requested.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending

claims is earnestly solicited.

Respectfully submitted,

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